

THE ORTHOPAEDIC INDUSTRY ANNUAL REPORT®

Introduction

Full report published May 2018

Complimentary for Members of ORTHOWORLD®, \$2,995 for all others.

Download and purchase from www.ORTHOWORLD.com.

INTRODUCTION

We estimate that 1,200 companies worldwide sell orthopaedic products. How many can you name? Close competitors or customers probably come to mind first. Of course, there's the top five. What about the French and Canadian companies that received their first joint reconstruction 510(k) clearances in 2017, or the Taiwanese and South Korean companies that received their first arthroscopy/soft tissue 510(k) clearances? Which spine companies launched products ex-U.S. last year? Orthopaedics is a vast market that addresses the treatment of musculoskeletal deformities, diseases, disorders and injuries in the global population. Products are used to treat arthritis, back pain, fractures, osteoporosis, scoliosis, soft tissue disorders, etc. Annually, we publish this report to detail the activity of the industry's largest players—from those on your mental list, to the startups you hadn't identified.

We understand that you're closely watching the decisions made by the largest orthopaedic companies. We are too. DePuy Synthes, Zimmer Biomet, Stryker, Smith & Nephew, Medtronic, Arthrex and, for the first time, NuVasive achieved orthopaedic revenue over \$1 billion in 2017. Our goal with this report is that you acquire new knowledge about the makeup of these companies, *and* you discover new competitors or customers and the actions they've taken. In writing the report, we wanted to answer questions often asked to us:

- What is the market share of the top companies?
- What is the revenue of the next-tier of orthopaedic companies, private and public?
- Who are the new companies that entered the U.S. market?
- What is the size of the ex-U.S. market?
- Where can I find a list of companies that play in my market?

Within this report, you'll find:

- Fifty revenue and market share exhibits. These include:
 - 2017 vs. 2016 estimates for the 24 largest companies (revenue above \$215 million) and their market share
 - 2017 vs. 2016 estimates for the top 10 players in each market segment (joint reconstruction knee, hip, and extremities; spine; trauma; arthroscopy/soft tissue; orthobiologics) and corresponding market share
 - 2017 U.S., EMEA, Asia Pacific and Rest of World revenue for the top seven companies and others
 - 2017 vs. 2016 estimates for the contract manufacturing sector and market share
 - 2018 through 2022 year-over-year projections for the industry as a whole, as well as each market segment

- A summary of influences that shape the industry and each market segment
- A recap of 2017 strategic activity, including acquisitions, regulatory clearances, product launches, patents, funding and studies/trials
- Lists of companies that play in each market segment and the subsegments within which they sell products

New in this installment of the report:

- Market drivers and advice regarding the current and critical opportunities and challenges driving the industry, as identified by ~200 orthopaedic professionals. These include:
 - Additive manufacturing
 - Ambulatory Surgical Centers (ASCs)
 - The European Union’s Medical Device Regulation (MDR)
 - Mergers & acquisitions
 - Reimbursement
 - Robotics, computer-assisted surgery
 - Surgeon and patient pre- and post-operation tools
 - Unique device identification (UDI)
- A Contract Manufacturing chapter that details the sector’s size and market forces. These companies are seen as an extension of device manufacturers’ operations; therefore, they face similar market influences, including consolidation, global expansion and personnel challenges.
- Market segment introductions authored by industry surgeons and specialists to provide you with expert alternative perspectives.
- A list of companies that received their first FDA 510(k) clearances and companies that received their first 510(k) clearance in a new market segment, as well as details on the company’s product and headquarter country.

About our Numbers

Before you begin, we would be remiss if we didn’t share a note about how we establish our market and individual company revenue estimates.

- We start with as-reported revenue numbers from public companies, privately-disclosed figures from non-public players and estimates based upon our knowledge of individual companies. We then “bucket” revenue into six orthopaedic segments (defined on the following page) in order to support apples to apples comparison. In short, our revenue figures do not appear as companies themselves report them.
- Revenue estimating and projecting is a moving target—not only for us, but for individual companies. Nearly every year, one public company recasts a portion of its revenue to provide greater—or

sometimes less—insight into its performance. Every year we get smarter about determining orthopaedic-specific revenue. For example, this year, we've removed DJO's bracing revenue from the report and provided greater insight into the performance of its joint reconstruction division. This is why we recommend that you always reference the latest installment of the report.

That said, we continually critique and seek validation of our numbers, which is why we believe that they are the most accurate representation of the orthopaedic industry. This is evidenced by the myriad questions we receive from analysts, investors and executives about our numbers.

About Our Market Segments

The segments addressed in this report are defined as follows.

Joint Reconstruction: Implants, instruments and surgical assistance systems, e.g. robotics and navigation, to replace or revise failed joints in the hip, knee, shoulder, elbow, wrist, ankle and digits

Spine: Implants and instruments and surgical assistance systems, e.g. robotics and navigation, to treat degenerative disc disease, herniated discs, scoliosis, vertebral fractures, etc.: pedicle screws, plates, rods, hooks, artificial discs, motion-preserving devices, vertebroplasty/kyphoplasty systems, etc.

Trauma: Implants and instruments for internal and external use (plates, screws, intramedullary nails, pins, wires, staples, external fixators, etc.); also known as Fracture Repair

Arthroscopy/Soft Tissue Repair: Equipment and implantables, including arthroscopes, cameras/visualization systems, fluid management, handheld instruments for removal of bone and soft tissue, radiofrequency systems; artificial ligaments, screws, anchors and tacks in metal and resorbable materials, polyetheretherketone (PEEK), etc.; also known as Sports Medicine

Orthobiologics: Biologic and biochemical products such as allograft and xenograft tissue, synthetic bone graft substitutes, autologous platelet/plasma systems, cell-based repair systems, growth factors, bone proteins, anti-adhesion technologies, hyaluronic acid and viscosupplements, with application across the market segments

Other: Contains craniomaxillofacial, bone growth stimulation and miscellaneous items like Zimmer Biomet's forgings and Accelero and Stryker's Performance Solutions. We constantly strive to refine this category in our ongoing effort to improve the accuracy of our market segment estimates.

The word "select" in exhibits within each chapter refers to products that companies chose to highlight strategically in press releases and earnings calls.